(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that conforms to the requirements prescribed by §432.5(a)(3) of this chapter.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions under which the layman can use the drug safely and efficaciously.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The bacitracin used in making the batch for potency, loss on drying, pH, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The bacitracin used in making the batch: 10 packages, each containing approximately 1.0 gram.

(*b*) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed for bacitracin zinc in §436.105 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the sample into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 20 to 25 milliliters of 1 percent potassium phosphate buffer, pH 6.0 (solution 1) and shake well. Allow the layers to separate. Remove the buffer layer and repeat the extraction procedure with each of three more 20- to 25-milliliter quantities of solution 1. Combine the buffer extractives in a suitable volumetric flask and dilute to volume with solution 1. remove an aliquot, add sufficient hydrochloric acid so that the amount of acid in the final solution will be the same as in the reference concentration of the working standard and further dilute with solution 1 to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated).

(2) *Moisture.* Proceed as directed in §436.201 of this chapter.

[42 FR 27232, Nov. 27, 1977, as amended at 50 FR 19920, May 13, 1985]

§§ 448.510b—448.510c [Reserved]

§448.510d Bacitracin-neomycin sulfate ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin-neomycin sulfate ointment contains bacitracin and neomycin sulfate in a suitable ointment base. Each gram contains 500 units of bacitracin and 3.5 milligrams of neomycin. Its bacitracin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of units of bacitracin that it is represented to contain. Its neomycin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of neomycin that it is represented to contain. The moisture content is not more than 0.5 percent. The bacitracin used conforms to the standards prescribed by §448.10(a)(1). The neomycin sulfate used conforms to the standards prescribed by §444.42(a)(1) of this chapter.

(2) *Labeling.* (i) On the label of the immediate container and on the outside wrapper or container, if any:

(*a*) The batch mark.

(*b*) The name and quantity of each active ingredient contained in the drug.

(*c*) An expiration date that conforms to the requirements prescribed by §432.5(a)(3) of this chapter.

(ii) On the label of the immediate container or other labeling attached to or within the package, adequate directions under which the layman can use the drug safety and efficaciously.

(3) *Requests for certification; samples.* In addition to complying with the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The bacitracin used in making the batch for potency, loss on drying, pH, and identity.

(*b*) The neomycin sulfate used in making the batch for potency, loss on drying, pH, and identity.

(*c*) The batch for bacitracin content, neomycin content, and moisture.

(ii) Samples required:

(*a*) The bacitracin used in making the batch: 10 packages, each containing approximately 1.0 gram.